First-In-Human Clinical Trials

Shortening your drug development timeline and decision making process

Data that is both accurate and timely is imperative for success at every stage of drug discovery and development. Our leading capability in conducting high quality early and late phase studies, combined with established expertise in bioanalysis, translational medicine, and pharmacometrics services makes QPS the perfect drug development partner for pharmaceutical and biotech organizations worldwide.

We provide state of the art facilities for conducting first-in-human (FIH) clinical trials in both healthy volunteers and patients and offer one of the world's largest Phase I site offerings with 480 beds on three continents; Europe, Asia, and North America.

Our protocols and linearly integrated preclinical and clinical drug development resources and services enable us to provide critical data from FIH studies quickly, accurately, and cost effectively. Our studies have validated uses for investigational products and provide invaluable safety and efficacy data.

For more information on FIH Clinical Trials, please contact our team.

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QPS Netherlands Phase 1 Unit – Site Specifics

General Information and History

- 16,000 square foot facility
- 58 beds
- Opened in September, 2004 (12 beds)
- Expanded in November, 2005 (12 beds)
- Expanded in May, 2012 (10 beds)
- Expanded in November, 2012 (24 beds)
- Hospital based
- Connected to hospital back-up generator
- Study timelines: 4 – 6 weeks from receipt of protocol to first dose

Sponsor Monitoring Areas

- Private monitor rooms (2 desks per room)
- Dedicated monitor conference room
- Dedicated copy machine
- DSL internet access
- Phone

Recruiting

- On-site call center with 3 stations, off-site call center with 10 stations
- Call center available 5 days a week from 08:00 – 21:00
- Recruiters are responsible for both outgoing and incoming calls
- Database of > 10,000 healthy subjects and > 400 patients
- Continuous advertising campaigns (both generic and study-specific) – dedicated website, bannering, Facebook, transit and print

IRB

- Parallel submission to competent authority (CCMO) and IRB
- Primarily using Stichting BeBo in Assen
- General turnaround time (TAT) is 2 weeks from submission to approval
- Stichting BeBo offers bimonthly meetings (first Tuesday and third Tuesday of each month)
- English as working language
- Translations being offered

Clinical Trial Pharmacy

- GMP certified Pharmacy
- Dutch Manufacturer's license covering the manufacture under contract and supply of Investigational Medicinal Products (IMPs)
- Dedicated Clinical Trial Pharmacist who is in charge of the pharmacy and all investigational medicinal products (IMPs)
- Two Qualified Persons
- Dispense from bulk medication for either open label or blinded studies using a master randomization list
- Clean room with a vertical laminar air flow cabinet (EU grade-A workstation) in a EU grade-B controlled background environment for aseptic drug preparations
- Controlled Substances license
- Key card access

On-site ADME Laboratory

- GLP laboratory
- Sample processing laboratory for urine, feces, plasma, whole blood, expired air and medication samples
- Liquid scintillation counter (Tri-Carb 2910, Perkin Elmer)
- Biological Oxidizer (Pakard 307 Sample Oxidizer, Perkin Elmer)
- HPLC-UV (1200 series, Agilent) with Radioflow Detection (Ramona Quattro Digital, Raytest)

Consenting

- 2 dedicated consent rooms
- 5 Dedicated consenters
- Small group consents
- One-on-one consenting

Screening

- Dedicated screening area
- 4 physical examination rooms
- Independent staff and equipment
- Sample processing laboratory

Outpatient Services

- 4 physical examination rooms
- Nurses' station
- Multifunctional procedure room for dosing and outpatient assessments
- Dayroom area with TV, reading materials and computers
- Sample processing laboratory

Local Laboratory

- Laboratories KCL Bioanalysis
- CCKL licensed
- Courier service multiple times each day
- On-site KCL Bioanalysis staff for QC
- Standard TAT (< 12 hours), STAT (< 12 hours)
- Electronic Data Transfer

Conduct Areas

- 4 separate conduct units (3 general, 1 ADME)
- 1 conduct unit designed for study procedures in center core area and housing around exterior
- Large nursing stations designed to oversee all participant areas
- Dining areas – meals are catered by an independent catering company, prepared on-site in dedicated kitchen
- Conduct areas
- Dayroom areas – big screen TV, computers with internet access, books and games.
- Synchronized clocks
- Mobile equipment
- IV infusion pumps
- Cardiac monitoring
- Centralized restrooms
- 24/7 nursing coverage
- Laundry facilities

Housing

- Unit 1 – 2 wards (both 17 beds)
- Unit 2 – 1 ward (24 beds)
- Individual lockers for participant's belongings
- Individual desks
- Cable TV with DVD players and video games
- DSL internet access
- Intercom system connected to nurses' station with emergency call buttons